



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Randox Laboratories Limited
c/o Pauline Armstrong
55 Diamond Road
Crumlin, County Antrim,
BT29 4QY
United Kingdom

AUG 24 2012

Re: k113747
Trade Name: Randox Opiates Assay
Randox Multidrug Calibrator Set
Randox Multidrug Controls, Level 1 and Level 2
Regulation Number: 21 CFR § 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Codes: DJG, DLJ, LAS
Dated: July 5, 2012
Received: July 13, 2012

Dear Dr Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

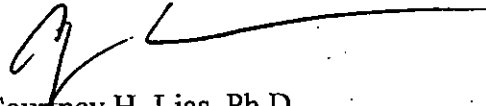
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k113747

Device Name: OPIATES ASSAY AND THE RANDOX MULTIDRUG CALIBRATOR SET
AND MULTIDRUG CONTROLS LEVEL 1 & LEVEL 2

Indication For Use:

Randox Opiates Assay: The Randox Laboratories Ltd. Opiates Assay is an in vitro diagnostic test for the qualitative and semi-quantitative analysis of Opiates in human urine. The cut off for both the qualitative and semi-quantitative application is 2000ng/ml for morphine to which the assay is calibrated. Qualitative and semi-quantitative results can be utilized in the diagnosis and treatment of Opiate use or overdose. The Randox Opiates Assay has been developed for use on the RX series analysers, which includes the RX Daytona and the RX Imola. This in vitro diagnostic device is intended for prescription use only.

The semi-quantitative mode is for purposes of (1) Enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as GCMS, or (2) Permitting laboratories to establish quality control procedures.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatograph/Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Randox Multidrug Calibrator Set: The Randox Multidrug Calibrator Set is for use on human urine samples. They are liquid calibrators containing Methamphetamine, Secobarbital, Methadone, and Morphine. There are 5 levels of calibrator. They have been developed for use in the calibration of Amphetamine, Barbiturates, Methadone and Opiate assays on the RX series analysers, which includes the RX Daytona and RX Imola. This in vitro diagnostic device is intended for prescription use only.

Randox Multidrug Controls, Level 1 & 2: The Randox Multidrug Controls, level 1 and 2 are for use on human urine samples. They are liquid controls containing Methamphetamine, Secobarbital, Methadone, and Morphine. There are 2 levels of controls. They have been developed for use in the quality control of Amphetamine, Barbiturates, Methadone and Opiate assays on the RX series analysers, which includes the RX Daytona and RX Imola. This in vitro diagnostic device is intended for prescription use only.


Prescription Use ✓
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k113747